AUG 1 6 2000

K002041

Section E

510(k) SUMMARY

Submitted by: Jensen Industries
50 Stillman Road
North Haven CT 06473
(203) 239-2090 phone
(203) 234-7176 fax
Contact: John Slanski

Date Prepared: December 9, 1999

Device Name: **Willi Geller Creation& AV Porcelain**
Common Name: Dental Porcelain
Classification: Class II
Product Code: EIH

Predicate Devices: Vitadur Alpha (Vident): 510(k) number K921623
Procera AllCeramic Porcelain (Nobelpharma): 510(k) number K944702
Willi Geller Creation Porcelain: 510(k) number K981490

Device Description

Willi Geller Creation& AV porcelain is a dental ceramic that is used by dental technicians to fabricate dental restorations by veneering of aluminum oxide-based cores. ***Willi Geller Creation& AV*** can also be used to fabricate ceramic inlays, onlays, and veneers. Data has been presented to demonstrate that the mechanical properties, chemical qualities, and the indications for use make ***Willi Geller Creation& AV*** substantially equivalent to the predicate devices VITADUR ALPHA, AllCeram, and *Willi Geller Creation& Porcelain.* The safety and effectiveness of ***Willi Geller Creation& AV*** , being determined by the chemical qualities and mechanical properties, is therefore equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2000

Mr. John Slanski
Manager, Research & Development
Jensen Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

Re: K002041
Trade Name: Willi Geller Creation & AV Porcelain
Regulatory Class: II
Product Code: EIH
Dated: June 30, 2000
Received: July 5, 2000

Dear Mr. Slanski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002041

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Jensen Industries Incorporated

510(k) Number (if known): K002041

Device Name: Willi Geller Creation& AV Porcelain

Indications For Use:

Willi Geller Creation& AV Porcelain is a ceramic material intended for veneering of aluminum oxide-based cores and substructures to form dental restorations, and for fabrication of ceramic dental inlays, onlays, and veneers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002041